

### Remarks

Claims 1-28 are pending, including new claim 28. Claims 1, 22-25 and 27, 28 are in independent form.

#### Allowable Subject Matter

Claim 27 is allowed. Claim 27 has been amended to change “resilient biasing mechanism” to “resilient biasing means” to accord with the specification, for example, paragraph [0011] of the published application.

Claims 6-7, 11-14, 16-21, 25 are objected to as being dependent upon a rejected base claim, but have been found to be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

In a September 1, 2010 telephone discussion with the Examiner, attempting to arrange an interview, Attorney for Applicants, Lawrence Sewell, asked the Examiner to clarify the status of independent claim 25, which was grouped with the dependent claims said to be allowable under the conditions described immediately above. The Examiner said that claim 25, being independent, is indeed allowed.

Claim 25 has been amended to change “adjustment means for adjusting” to simply “means for adjusting” to be in closer accord with the specification.

#### Drawings

The drawings are objected to because Fig. 6A is not labeled. A Replacement Sheet is submitted herewith that labels Fig. 6A.

The drawings are objected to because they fail to show the curved elements 15 and 17 being curved in at least figures 1 and 2. A Replacement Sheet is submitted herewith that shows the curved elements in Figs. 1 and 2.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: "resilient biasing mechanism". Attorney for Applicants seeks clarification of this objection, since the phrase

"resilient biasing mechanism" does not appear in the specification or the drawings. The phrase was inserted in the claims by amendment, but has been removed; it would seem that this removal sufficiently addresses the drawing objection.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: "adjustment means (claim 24). Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121 (b) are required." Although the objection states that a reference character of the drawings is not mentioned in the description, there is no reference character in the drawings labeled "adjustment means". As a result, the objection is interpreted to be that there needs to be a reference character assigned in the description to the term "adjustment means". Accordingly the specification has been amended to include such a reference character.

### Specification

The specification has been objected to as failing to provide proper antecedent basis for the claimed subject matter. Correction of the following is required: adjustment means (claim 24). Applicants wish to point out that "adjustment means" is found in paragraph [0012] of the published application, and it is submitted that the description there, namely "the adjustment means may comprise a screw adjustment means that suitably is screw-threadedly adjustable axially toward or away from the clutch mechanism", clearly relates the "adjustment means" to the Description of the Preferred Embodiment paragraph [0044]. Accordingly, it is requested that the requirement for correction of claim 24 be withdrawn.

### Claim Rejections – 35 USC 112

Claims 4 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 4, "the resilient biasing means" was found to conflict with the "biasing force" of claim 1. It is submitted that such a conflict no longer exists in view of amendments to claim 1.

The Official Actions states that claim 26 was not understood and asks what is the biasing mechanism which includes means for applying at least two biasing forces? Claim 26 has been amended to a form which is intended to be clear and in which the means for applying a first biasing force is supported by the specification for example at paragraphs [0016] and [0041]-[0042] of the published application. The means for applying a second biasing force is supported by the specification for example at paragraphs [0011]-[0012] and [0044].

In view of the preceding, it is requested that the rejection of claims 4 and 26 under section 112 be withdrawn.

#### Claim Rejections - 35 U.S.C. 102

Claims 1-5, 8-10, 15, 22-24 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Gramnas (6,302,918).

The Action states that the Gramnas apparatus “is in a fixed relationship at a first force level and upon a higher predetermined force which exceeds the resilient biasing mechanisms (elements 19 and 20), the proximal and distal component can rotate relatively.”

Gramnas states at column 3, lines 14-21, “The second resilient member 19 has in unloaded position a very limited mobility in radial direction in the hollow space 17, which means that also rotational movements between the telescopic members 10 and 11 are elastically damped. At a torsional force right-left the resilient member 19 is compressed and admits depending on elastic stiffness and torsion force a rotation of between 0-30 .degree. with a gradually increasing resistance.”

Claim 1 has been amended to emphasize that when the proximal and distal components are disengaged by the recited structure, when the limb is subjected to a force in excess of a threshold, then at least one of tilting or rotational articulation can happen. Gramnas does not disclose any such mechanism. For the Gramnas apparatus to rotate more, the resilient sleeve 19 attached to telescopic member 10 is engaged, with progressively greater force, by the walls of hollow space 17 of telescopic member 11. Please note the “increasing resistance” stated by Gramnas above. The present invention operates in a different fashion not suggested by the cited

art, and it is submitted that the language of amended claim 1 unambiguously expresses the difference.

The apparatus of Gramnas cannot provide the fail-safe operation recited in claim 1. It is clear from an inspection of Gramnas, along with the description quoted above, that as force on the Gramnas device increases, there is a level of force at which no significant amount of rotation will happen. At that point and above, the Gramnas prosthesis will be subject to being rotated by the external force against the attachment of the prosthesis to the bone, with potential harm to the patient. By contrast, at a threshold level of force and above, the presently claimed invention will allow rotation between the proximal and distal components, so as to avoid application of the external force to the attachment between bone and prosthesis. The Gramnas device appears to provide some cushioning for lower level forces, but does not suggest the kind of protection of the present invention for larger forces, and therefore, provides no way to achieve it.

In addition, it is respectfully submitted that Gramnas does not disclose holding proximal and distal components in fixed relation during normal use of the prosthetic limb. The telescopic elements 10 and 11 presumably would not rotate with respect to each other in the unusual case that the torsional force were essentially zero, but they are not held in a fixed relation in the sense of being prevented from moving, as disclosed and claimed by Applicants. Otherwise, for even small torsional forces experienced in normal use and below a threshold safe level, the telescopic elements rotate with respect to each other – in the range 0-30 degrees as quoted above.

For the reasons given, it is submitted that claim 1 as amended is not anticipated by Gramnas and that neither are claims 2-5, 8-10, 15, and 26, since they are dependent on claim 1.

New claim 28 is generally of the same structure as claim 1, but recites a coupling body coupling both tilting and an axial rotational articulation, rather than “at least one of” as in claim 1. Claim 28 is submitted to be patentable in view of Gramnas for the reasons given in connection with claim 1. In addition, while Gramnas does describe compensating for very limited tilt in order to avoid seizing of the device, there is no disclosure of controlling large bending forces in excess of a threshold by allowing tilting articulation. For these reasons, it is submitted that claim 28 is allowable in view of Gramnas.

Claim 22 has been amended and is believed to be clearly unanticipated by the disclosures of Gramnas. As with claim 1, the recitations of claim 22 emphasize that when the proximal and distal components are disengaged by the recited structure, when the limb is subjected to a force in excess of a threshold, then at least one of tilting or rotational articulation can happen. Also as in claim 1, there is “a biasing force to hold the proximal and distal components in engagement and thereby couples together the proximal and distal components so that one is in a fixed angle relation to the other in normal use, the effect of the biasing force being opposed by any applied bending force, thereby allowing the proximal and distal components to disengage with freedom to articulate.” As pointed out above, Gramnas discloses increasing engagement in response to increasing external force.

Claim 23 has been amended to describe the “clutch-like mechanism” in more detail and to clarify that disengagement of the clutch-like mechanism upon excessive external force allows rotation. As described above, elements of Gramnas, whether or not they be considered “clutch-like” become increasingly engaged in response to increasing external force. Accordingly, it is believed claim 23 is not anticipated or even suggested by Gramnas.

Claim 24 has been amended to recite “screw adjustment”. It is submitted that this cannot be read on Gramnas exchanging resilient sleeve 19 for another. Accordingly, it is believed claim 23 is not anticipated by Gramnas.

For the reasons given, it is submitted that that claims 1-5, 8-10, 15, 22-24, 26 and new claim 28, all as amended, are not anticipated by Gramnas.

Further, it is submitted that claims 6-7, 11-14, 16-21, indicated to be allowable if in independent form, are allowable as dependent ultimately on claim 1.

Claim 22 is rejected under 35 U.S.C. 102(b) as being anticipated by Weddendorf (5,314,500).

Claim 22 as amended makes clear that it is the effect of the biasing force being opposed by an applied bending force which is urging the limb toward a tilting and/or rotational articulation that allows the proximal and distal components to disengage with freedom to articulate. It is submitted that this is not disclosed or suggested by Weddendorf and is not anticipated by the possibility of pin 66 breaking.

Conclusion

In view of the above amendments and remarks, allowance of all pending claims is respectfully requested.

If at any time the Examiner wishes to discuss this application, he is invited to call V. Lawrence Sewell at (214) 349-8180.

Respectfully submitted,



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